

February 11, 2004



the Children's Hospital
AT ALBANY MEDICAL CENTER

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Mark B. McClellan, MD, PhD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
5600 Fishers Land
Rockville, MD 20857

02-23-04A09:55 RCVD

Dear Commissioner McClellan:

As a practicing pediatrician and member of physicians for Reproductive Choice and Health® (PRCH), I strongly support the overwhelming evidence-based and public health imperative for over-the-counter access to emergency contraceptive pills (ECPs).

Contraception, regrettably, is neither universal nor fail-proof. Unintended pregnancies occur in both the small percentage of women who don't use contraception, and in women for whom contraception fails. Of all the women who experienced an unintended pregnancy, more than half – 53 percent – were using contraception at the time of conception.

Extensive research also demonstrates that ECPs are extremely safe, including when self-administered. The hormones in ECPs have been used for more than thirty years as daily birth control by tens of millions of women, and serious complications have been extremely low.

Medical decisions should be rooted firmly in scientific evidence. Research on emergency contraception – including numerous randomized trials, data on actual use, and label-comprehension studies – has revealed that prescription-only status of ECPs is both gratuitous and harmful. Prolific research on ECPs documents their safety, efficacy, and ease-of-use, along with the economic benefits of OTC status for individuals, institutions, and public systems. The Institute of Medicine stated that establishing "evidence-based" medicine should be at the forefront of modern medicine's agenda, and has advocated in favor of aggressive efforts to reduce unintended pregnancy rates in America. The FDA can bring the medical community one step closer to reaching both goals by acknowledging the overwhelming evidence and granting OTC status to ECPs.

Professional and public support of the OTC switch is obvious, as more than 70 organizations are signatories to the 2001 Citizen's Petition for Status Change for Emergency Contraception. Among the numerous medical and public health organizations supporting the switch are:

AMA
ACOG
Association of Reproductive Health Professionals
American Academy of Pediatrics
American Medical Women's
Association, the American Nurses Association
National Association of Nurse Practitioners in Women's Health
American Public Health Association
Planned Parenthood
Federation of America
Black Women's Health Imperative
Advocates for Youth
American Pharmaceutical Association
Physicians for Reproductive Choice and Health®.

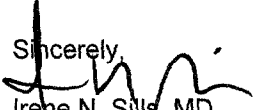
Condoms and spermicides are widely available over-the-counter. As a product that could drastically reduce the rate of unintended pregnancy, ECPs should share their over-the-counter

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status. Simply stated, emergency contraception is effective and safe and deserves to be available over-the-counter. I highly support over the counter status, and hope the FDA will follow science and make this a reality.

Sincerely,



Irene N. Silis, MD
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